

LOW ENDOTOXIN WIPES

Berkshire's new line of low endotoxin cleanroom wipes have been engineered to meet the specific requirements of the pharmaceutical, healthcare and medical device industries.

What is a pyrogen (endotoxin)?

IEST-RP-CC023.2 defines a pyrogen as "A substance capable of producing fevers. The most common pyrogens are endotoxins, a class of lipopolysaccharides that comprise the outer wall of Gram-negative bacteria and are themselves byproducts of cell metabolism."

Endo - Internal Toxin - Poison

Lipid A is the most toxic component of a gram-negative bacteria. It is embedded internally in the living bacteria.

When bacteria is killed through cleaning, the outer cell wall detritus is released and the dead cell becomes toxic. It needs to be removed from the surface.

What are common sources of endotoxins?

Common sources of endotoxins are water, soil, vegetation, raw materials, poor equipment sanitization and maintenance practices.

What are examples of gram-negative endotoxins?

Burkholderia, Pseudomonas, Ralstonia, Escherichia, Serratia, Stenotrophomonas

How do you test wipers for bacterial endotoxins?

Berkshire uses the LAL – Limulus Amebocyte Lysate test.

FDA Guidance for Industry: Pyrogen and Endotoxins Testing

"For more than 30 years, FDA has accepted the use of Limulus Amoebocyte Lysate LAL test for endotoxins in lieu of the rabbit pyrogens test."

What is the frequency of endotoxin testing?

Berkshire tests each lot for endotoxins.

What are your guaranteed endotoxin limits?

<20 EU/device – <0.5 EU/mL

FDA Guidance for Industry: Pyrogen and Endotoxins Testing

"For medical devices...the limit is 0.5 EU/mL or 20 EU/device for products that directly or indirectly contact the cardiovascular system and lymphatic system"

How is the Water For Injection (WFI) prepared?

The WFI is prepared by a validated aseptic sterile filtration process. This complies with the industry's Sterility Assurance Level (SAL) of 10-3. The specification for Endotoxin USP is ≤0.025 EU/mL.

PRICING & AVAILABILITY

To learn more about Berkshire's low endotoxin wipes, contact a Technical Sales Representative, call (+44) 870-757-2877. Or send an email to enquiries@berkshire.uk.com.

BERKSHIRE CORPORATION

ITEM NUMBER	PRODUCT/ PACKAGING
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Sealed edge, cleanroom laundered, polyester knitted, dry wiper

MSVP09098LE	MicroSeal® VP – 9x9" (22x22cm) 150 SHTS /PK, 8 PKS/CS
MSSS09098LE	MicroSeal SuperSorb® – 9x9" (22x22cm) 100 SHTS /PK, 8 PKS/CS

Sterile, sealed edge, cleanroom laundered, polyester knitted, dry wiper

GWSSST16LE	Gamma® Wipe SuperSorb® – 12x12" (30x30cm), 10 SHTS /PK, 16 PKS/CS
GWPST25LE	Gamma Wipe® VP – 12x12" (30x30cm) 20 SHTS /PK, 25 PKS/CS

Sealed edge, cleanroom laundered, polyester knitted, presaturated WFI wiper

SPXVP00112LE	SatPax® MSVP – 9x9" (22x22cm) 30 SHTS /PK, 12 PKS/CS
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Sterile, sealed edge, cleanroom laundered, polyester knitted, presaturated WFI wiper

SSPVP00112LE	Sterile SatPax® MSVP – 9x9" (22x22cm) 30 SHTS /PK, 12 PKS/CS
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Nonwoven, dry wiper

MFLP090912LE	MicroFirst® LP – 9x9" (22x22cm) 150 SHTS /PK, 12 PKS/CS
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Sterile, Nonwoven, dry wiper

GWMFLPST25LE	Gamma Wipe® MFLP – 12x12" (30x30cm) 20 SHTS /PK, 25 PKS/CS
GWMPNW5ST25LE	Gamma Wipe® MPNW – 12x12" (30x30cm) 20 SHTS /PK, 25 PKS/CS

Nonwoven, presaturated WFI wiper

SPXMFLP00112LE	SatPax® MFLP – 9x9" (22x22cm) 75 SHTS /PK, 12 PKS/CS
SPX55000624LE	SatPax® 550 – 9x11" (22x28cm) 50 SHTS /PK, 24 PKS/CS

Sterile, nonwoven, presaturated WFI wiper

SSPMFLP00124LE	Sterile SatPax® MFLP – 9x9" (22x22cm) 30 SHTS /PK, 24 PKS/CS
SSP55000524LE	Sterile SatPax® 550 – 9x11" (22x28cm) 50 SHTS /PK, 24 PKS/CS

LOW ENDOTOXIN VITAL STATISTICS BY SUBSTRATE

100% POLYESTER KNITTED 2-PLY WIPER

	BASIS WEIGHT	CALIPER	FIBERS	PARTICLES $\geq 0.5\mu\text{m}$	SORBENCY			NON-VOLATILE RESIDUE		IONS				
ITEM NUMBER	g/m ₂	μm	$\geq 100\mu\text{m}/\text{cm}^2$	x10 ³ /cm ²	CAPACITY mL/m ²	EFFICIENCY mL/g	RATE SECONDS	H ₂ O (g/m ²)	IPA (g/m ²)	Na ⁺	K ⁺	Ca ⁺⁺	Mg ⁺⁺	Cl ⁻
GWSSST16LE	267	765	0.14	0.49	1030	3.9	1	0.0092	0.017	0.31	0.023	0.059	0.01	0.27
MSSS09098LE	267	765	0.14	0.49	1030	3.9	1	0.0092	0.017	0.31	0.023	0.059	0.01	0.27

100% POLYESTER KNITTED WIPER

	BASIS WEIGHT	CALIPER	FIBERS	PARTICLES $\geq 0.5\mu\text{m}$	SORBENCY			NON-VOLATILE RESIDUE		IONS				
ITEM NUMBER	g/m ₂	μm	$\geq 100\mu\text{m}/\text{cm}^2$	x10 ³ /cm ²	CAPACITY mL/m ²	EFFICIENCY mL/g	RATE SECONDS	H ₂ O (g/m ²)	IPA (g/m ²)	Na ⁺	K ⁺	Ca ⁺⁺	Mg ⁺⁺	Cl ⁻
GWVPST25LE	130	464	0.038	0.53	506	3.9	1	0.0037	0.0092	0.2	0.016	0.031	0.0065	0.18
MSVP09098LE	130	464	0.038	0.53	506	3.9	1	0.0037	0.0092	0.2	0.016	0.031	0.0065	0.18
SPXVP00112LE	130	464	0.038	0.53	506	3.9	1	0.0037	0.0092	0.2	0.016	0.031	0.0065	0.18
SSPVP00112LE	130	464	0.038	0.53	506	3.9	1	0.0037	0.0092	0.2	0.016	0.031	0.0065	0.18

100% POLYESTER MICROFIBER NONWOVEN WIPER

	BASIS WEIGHT	CALIPER	FIBERS	PARTICLES $\geq 0.5\mu\text{m}$	SORBENCY			NON-VOLATILE RESIDUE		IONS				
ITEM NUMBER	g/m ₂	μm	$\geq 100\mu\text{m}/\text{cm}^2$	x10 ³ /cm ²	CAPACITY mL/m ²	EFFICIENCY mL/g	RATE SECONDS	H ₂ O (g/m ²)	IPA (g/m ²)	Na ⁺	K ⁺	Ca ⁺⁺	Mg ⁺⁺	Cl ⁻
GWMPNW5ST25LE	52.2	198	18.8	1.6	234	4.5	6.0	0.0044	0.0040	37	5.3	48	9.3	48

58% POLYESTER / 42% LYOCELL NONWOVEN WIPER

	BASIS WEIGHT	CALIPER	FIBERS	PARTICLES $\geq 0.5\mu\text{m}$	SORBENCY			NON-VOLATILE RESIDUE		IONS				
ITEM NUMBER	g/m ₂	μm	$\geq 100\mu\text{m}/\text{cm}^2$	x10 ³ /cm ²	CAPACITY mL/m ²	EFFICIENCY mL/g	RATE SECONDS	H ₂ O (g/m ²)	IPA (g/m ²)	Na ⁺	K ⁺	Ca ⁺⁺	Mg ⁺⁺	Cl ⁻
GWMFLPST25LE	70.2	299	20	4.1	377	5.4	3	0.021	0.0092	13	1.2	20	5.8	11
MFLP090912LE	70.2	299	20	4.1	377	5.4	3	0.021	0.0092	13	1.2	20	5.8	11
SPXMFPLP00112LE	70.2	299	20	4.1	377	5.4	3	0.021	0.0092	13	1.2	20	5.8	11
SSPMFLP00124LE	70.2	299	20	4.1	377	5.4	3	0.021	0.0092	13	1.2	20	5.8	11

100% POLYPROPYLENE NONWOVEN WIPER

	BASIS WEIGHT	CALIPER	FIBERS	PARTICLES $\geq 0.5\mu\text{m}$	SORBENCY			NON-VOLATILE RESIDUE		IONS				
ITEM NUMBER	g/m ²	μm	$\geq 100\mu\text{m}/\text{cm}^2$	x10 ³ /cm ²	CAPACITY mL/m ²	EFFICIENCY mL/g	RATE SECONDS	H ₂ O (g/m ²)	IPA (g/m ²)	Na ⁺	K ⁺	Ca ⁺⁺	Mg ⁺⁺	Cl ⁻
SSP55000524LE	35.4	204	0.48	4.8	196*	5.5*	10*	0.0032	0.015	0.42	0.2	0.47	0.038	0.8
SPX55000624LE	35.4	204	0.48	4.8	196*	5.5*	10*	0.0032	0.015	0.42	0.2	0.47	0.038	0.8

Notes:

- Technical data represented in this table are typical values at the time of publication. These should not be used as product specifications.

- Due to differences in test methods applied and equipment utilized by different wiper manufacturers, valid product comparisons may only be obtained through side-by-side testing in the same test facility, under similar conditions.

- Third party testing can be performed upon request.